Remarks/Arguments:

Objections

The Action objects to Applicants' amendment filed on February 15, 2006 under 35 USC 132(a) because it purportedly introduces new matter. While Applicant maintains its position that International Publication Number WO 00/43020 is identical to USSN 09/233,379, Applicants have amended the specification to replace WO 00/43020 with the originally recited USSN 09/233,379. In view of this amendment, Applicants respectfully submit that this rejection no longer applies.

Rejection – 35 USC 112

The rejection of claims 46 and 48-51 under 35 USC 112, second paragraph, from the previous office action is maintained. The rejection of claim 49 under 35 USC 112, second paragraph, from the previous office action is withdrawn. The Action, however, maintains that the claims are rejected because of the indefiniteness of the term "active" egg fraction, and that the phrase "partially purified anti-inflammatory fraction of the egg" is undefined.

Initially, and solely for the purpose of expediting prosecution of the present application, Applicants have cancelled claim 48, thus rendering null the rejection based on the lack of a definition for "partially purified anti-inflammatory fraction of the egg".

Regarding the remainder of this rejection, the Examiner asks what component is the "active fraction" or "anti-inflammatory fraction"? The Examiner then states that the examples show a whole egg, yet the "active fraction" and the "anti-inflammatory fraction" are not identified. Applicants respectfully traverse.

As set forth in the claims and argued by Applicant in response to the previous office action, the active fraction of the egg is that fraction containing supranormal levels of an anti-inflammatory composition. The anti-inflammatory composition is clearly defined on page 11, lines 16-18 of the present application as meaning "the composition disclosed in U.S. Serial Number 09/233,379 and herein, which counteracts or suppresses the inflammatory process." The Examiner suggests that while the new limitation (i.e. supranormal levels of the anti-inflammatory factor) is a further component of the egg fraction, it does not define what the

active fraction is. Applicants respectfully traverse and submit that the active egg fraction is exactly that, an active egg fraction. As set forth by the Federal Circuit, one must define a compound by "whatever characteristics sufficiently distinguish it." *Amgen Inc. v. Chugai Pharmaceutical*, 927 F2d 1200, 1206 (Fed Cir 1991). In *Amgen*, the Federal Circuit went on to state that conception occurs when "one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it." *Id* at 1206. Applicants submit that the "active egg fraction" is defined in the present application as that fraction of the egg that contains supranormal levels of an anti-inflammatory factor, wherein the terms "anti-inflammatory factor" and "supranormal levels" are clearly defined. These component parts of the "active egg fraction" therefore are characteristics that distinguish the claimed active egg fraction from other potential active fractions of an egg.

The Examiner then suggests that the new limitation itself is indefinite because "supranormal levels of an anti-inflammatory composition" is not defined in the specification. Moreover, the Examiner suggests that the term "supranormal" is a term that lacks comparative basis. Applicant respectfully disagrees and initially directs the Examiner to page 11, lines 13-18 of the present application wherein definitions for both the terms "supranormal levels" and "anti-inflammatory composition" are provided. Further, the definition of "supranormal levels" is indeed provided in a comparative fashion as meaning "levels *in excess of those found in eggs of egg-producing animals not maintained in a hyperimmune state.*" (page 11, lines 13-14) (Emphasis added). Even further, Applicants direct the Examiner's attention to page 14, lines 28-34 of the present application, which states that the supranormal levels of the anti-inflammatory composition *only arise* upon induction of a hyperimmune state.

Finally, the Examiner states that WO 00/43020 cannot be relied upon to define any terms in the instant application because the incorporation by reference is improper. In view of the amendment made to re-insert the original USSN 09/233,379 in place of WO 00/43020, Applicants respectfully traverse this portion of the rejection.

As set forth in 37 CFR 1.14(a)(1)(vi) (MPEP 103 (IV)), a member of the public is permitted to obtain a copy of pending application as originally filed (as well as an abandoned, unpublished application under 37 CFR 1.14(a)(1)(iv)), if the application is identified in a U.S.

patent application publication. USSN 09/233,379 was pending at the time of filing of the present application and was thereafter properly identified in the publication of the present application by its designated US serial number. As such, USSN 09/233,379 is a publicly available document that can be incorporated by reference.

In order to properly identify that USSN 09/233,379 is incorporated by reference, Applicants have amended the specification by adding the language "which is incorporated by reference herein" after USSN 09/233,379, in accordance with 37 CFR 1.57(g).

Essential material can be incorporated by reference by a publicly available patent application so long as the patent application itself does not incorporate such essential material by reference (see 37 CFR 1.57(c)). In this case, USSN 09/233,379 can be properly relied upon to provide a definition for the term "anti-inflammatory factor".

In conclusion, the terms "active egg fraction," "supranormal levels" and "anti-inflammatory composition" are all properly defined and supported by the present application. Therefore, Applicants respectfully request that the rejection of claims 46 and 48-51 under 35 USC 112, second paragraph, be withdrawn.

Rejection 35 USC 102

Claim 46 remains rejected under 35 USC 102(b) as being anticipated by Kondo et al. (USPN 4,367,309, "Kondo"), for reasons of record. In particular, the Examiner states that because the claims lacks a clear definition of "active egg fraction". Applicants respectfully traverse.

As set forth in the paragraphs above, the term "active egg fraction" is indeed clearly defined by the specification to mean a fraction of a hyperimmunized egg that contains supranormal levels of an anti-inflammatory composition. There is no disclosure whatsoever in Kondo of the anti-inflammatory fraction presently claimed, let alone supranormal levels of said fraction in the glycoprotein of Kondo. As such, the present claims cannot be anticipated by Kondo, and Applicant respectfully requests that the rejection of claim 46 35 USC 102(b) as being anticipated by Kondo be withdrawn.

Rejection 35 USC 103

The rejection of claims 46-51 under 35 USC 103(a) as being unpatentable over Adalsteinsson et al. (WO 99/36077, "Adalsteinsson") in view of Yue (US 6,251,863), is maintained for the reasons of record. Applicants respectfully disagree.

Initially, the Examiner maintains the position that, because the specification does not clearly define "active egg fraction" nor "supranormal levels of an anti-inflammatory composition", the anti-inflammatory fraction is interpreted as any egg fraction of a yolk with anti-inflammatory activity. In view of the argument presented above, Applicants respectfully submit that these terms are clearly defined and do indeed find proper support in the present application. As such, the anti-inflammatory fraction of the present invention is not merely any egg fraction of a yolk with anti-inflammatory activity, and is instead the specifically identified active egg fraction comprising supranormal levels of the anti-inflammatory factor as described in USSN 09/233,379, which is incorporated by reference.

Aside from the distinguishing aspects noted above, Applicants submit that there is no motivation to combine the Adalsteinsson and Yue references, nor would such combination be expected to result in the synergistic reduction of inflammation in the joints as provided for in the present application. As argued by Applicants in response to the previous office action, there would be no need in Yue for the use for the hyperimmune egg of Adalsteinsson as there is no need to protect the gastrointestinal tract from damage by glucosamine. Adalsteinsson specifically teaches the use of the hyperimmune egg to protect the gastrointestinal tract from damage resulting from NSAIDs or DMARDs. NSAIDs and DMARDs are well known in the art to cause severe gastrointestinal damage, especially when taken in high doses. There is no such effect/damage caused by glucosamine, and, as such, there would be no motivation for one having skill in the art to turn to Adalsteinsson for use of the hyperimmune egg together with Yue's disclosure of glucosamine. In response, the Examiner has stated that it would have been obvious to substitute the glucosamine sulfate of Yue for Adalsteinsson's NSAIDs or DMARDs because one would have been motivated to by Yue's teaching that glucosamine sulfate is a preferable treatment for joint inflammation instead of NSAIDS.

While Applicants agree that glucosamine may in certain instances be a preferential treatment for joint inflammation, those instances generally relate to situations when the user

wants to avoid gastrointestinal inflammatory damage, and as argued above, the hyperimmune egg of the present invention is administered together with NSAIDs or DMARDs in Adalsteinsson to help ease such GI inflammation. The critical point, however, is that the hyperimmune egg of Adalsteinsson provides inflammatory protection *within the gastrointestinal tract*. There is no mention or suggestion that in Adasteinsson that the hyperimmune egg has any affect outside of the gastrointestinal tract, i.e. the joints. In other words, there is no mention or suggestion that Adasteinsson's hyperimmune egg crosses the gastrointestinal lining and provides a systemic effect on other areas of the body. As such, even if glucosamine sulfate is the preferred method for treating joint inflammation in a particular subject, there would be no motivation to combine it with the hyperimmune egg of Adalsteinsson to treat joint inflammation because the egg of Adalsteinsson is not known to affect the joints.

In view of the above, Applicants respectfully request that the rejection of claims 46-51 under 35 USC 103(a) as being unpatentable over Adalsteinsson et al. in view of Yue be withdrawn.

Conclusion

The foregoing is believed to be fully responsive to this office action. The embodiments presented are believed to be allowable over the prior art of record. Consideration and allowance of the claims is respectfully requested.

If the Examiner believes that a telephone conference with Applicants' attorneys would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Respectfully submitted,

Basil S. Krikelis
Registration No. 41,129
Attorney for Applicant(s)

Dated: October 17, 2006

BSK/rls

McCarter & English, LLP
Citizens Bank Center
919 N. Market Street
Suite 1800
P.O. Box 111
Wilmington, DE 19899